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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,900	02/12/2002	Isabelle Arnould-Reguigne	03806.0537	3572

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EXAMINER	
EMCH, GREGORY S	
ART UNIT	**PAPER NUMBER**
1649	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/072,900	ARNOULD-REGUIGNE ET AL.	
	Examiner	Art Unit	
	Gregory S. Emch	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7-9,12,13,16-25,41-43,47 and 51-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7-9,12,13,16-25,41-43,47 and 51-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 21 December 2006 has been entered.

Response to Amendment

Claims 1, 3, 5, 7, 8, 13, 47, 52 and 53-63 have been amended, and claim 2 was canceled as requested in the amendment filed on 21 December 2006. Following the amendment, claims 1, 3-5, 7-9, 12, 13, 16-25, 41-43, 47 and 51-63 are pending in the instant application.

Claims 1, 3-5, 7-9, 12, 13, 16-25, 41-43, 47 and 51-63 are under examination in the instant office action.

The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicants' response and withdrawn.

Claim Rejections - 35 USC § 101, 112, first paragraph

The rejections of claims 1, 3-5, 7-9, 12, 13, 16-25, 41-43, 47 and 51-63 under 35 U.S.C.112, first paragraph and 35 U.S.C. 101 are maintained for the reasons of record and as set forth below.

At p.7 of the reply filed 21 December 2006, Applicants assert that because the instant gene is mapped to the same chromosomal region of various diseases, including ichthyosis, Applicants conclude that the gene is a marker for those disorders. Applicants also assert that the instant application describes polymorphisms of the ABCA12 gene that enables the artisan to identify different forms of the gene. Further, Applicants assert that there are discernable markers for ABCA12, and said markers can be used for diagnosing a disorder mapping to that same region or which is found to be linked to a polymorphism of ABCA12. Applicants also submit a Declaration by Dr. Nicholas Duverger, who is asserted to be one of ordinary skill in the art. Applicants and Dr. Duverger assert that based on the teachings of the specification, the instant inventors possessed a diagnostic assay for diseases that map to the same chromosomal region where the ABCA12 gene resides. Thus, Applicants conclude that the instant application provides a number of specific, substantial and credible uses of the nucleic acids of interest.

Applicants' arguments and affidavit have been fully considered and are not found persuasive.

Even though Lefevre et al. confirm that ABCA12 is associated with lamellar ichthyosis, the specification neither teaches nor suggests the missense mutations as

taught by Lefevre et al. Instead, the specification is completely silent as to using ABCA12 to diagnose lamellar ichthyosis. The instant affidavit is not persuasive because the level of skill in the art cannot be relied upon to establish utility for the claimed invention. See In re Kirk, 153 USPQ 48, 53 (CCPA 1967) quoting the Board of Patent Appeals:

> 'We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.'

Even though ABCA12 is associated with lamellar ichthyosis, Applicants have not explicitly taught that ABCA12 would be useful in the treatment of the disease or that assaying for ABCA12 mutations would be useful for diagnosing lamellar ichthyosis. Further research would be required to determine if and how ABCA12 and the instant variants would be useful in the treatment or diagnosis of such a disorder.

The evidence (publication and declaration) is insufficient to overcome the rejections, in part, because **the evidence is not commensurate in scope with the claims**. The claims are directed to a genus of polynucleotides, whereas the evidence only indicates that certain sequences are associated with a specific disease. Further, this specific disease is not commensurate with the scope of the teachings in the specification, since the specification only refers to a relatively large chromosomal location, which encompasses markers and loci for genes other than the one disclosed and may correlate with other genetic diseases, not only ichthyosis.

2) See MPEP 2107.01 (Starting at "Thus"):

> Thus a 'substantial utility' defines a 'real world' use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a 'real world' context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a 'substantial utility' define a 'real world' context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a 'real world' context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a 'real world' context of use and, therefore, do not define 'substantial utilities':
>
> (A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;
>
> (B) A method of treating an unspecified disease or condition;
>
> (C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility;
>
> (D) A method of making a material that itself has no specific, substantial, and credible utility; and
>
> (E) A claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility."

The specification only asserts that the polynucleotide has utility in diagnosing disease *in general*, and not icthyosis *in particular*. The publication evidences that further research was required after the filing date to reasonably confirm the real-world use, and to identify the disease linked to the disclosed sequence. Thus, the asserted utility in disease diagnosis is not substantial.

The rejection of claims 1, 3-5, 7-9, 12, 13, 16-25, 41-43, 47 and 51-63 under 35 U.S.C. 112, first paragraph for lack of enablement is maintained for reasons of record and as set forth above. Specifically, since the claimed invention is not supported by either a specific, and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, assuming arguendo that claims 3-5, 41-43, 47 and 51 were enabled, as referred to previously; the claims are not enabled for their full scope. Said claims are overly broad in the recitation of percent identity, hybridizing nucleic acids and functional limitations, since insufficient guidance is provided as to which of the myriad of nucleic acid species encompassed by the claims will retain the characteristics of either binding ATP, comprising a transmembrane domain or being an ABCA member. Further, the art does not provide compensatory teachings to enable the artisan to practice the invention commensurate in scope with the current claims.

The rejection of claims 3-5, 41-43, 47 and 51 under 35 U.S.C. 112, first paragraph, for lack of written description is maintained for reasons of record and as set forth below.

At p.8 of the reply filed 21 December 2006, Applicant asserts, "the specification teaches the association of ABCA12 with certain linked markers. Thus, any one fragment can be mapped to determine whether that nucleic acid retains the property of mapping to the chromosomal region where the genomic copy of the gene resides. Also, the

instant specification teaches association of the ABCA12 gene expression with markers of skin and epithelium.

Applicants' arguments have been fully considered and are not found persuasive.

The only functional limitations of the instant claims (e.g., claim 3) are that the proteins be encoded by the gene, comprise a transmembrane domain or be an ABCA member. Thus, such nucleic acid sequences could encode polypeptides that vary greatly from that of ABCA12. Further, the specification does not teach the skilled artisan how to make derivatives of ABCA12 that have the same function as ABCA12. In addition, the specification does not provide a patentable utility or function for ABCA12.

A genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v Eli Lilly & Co,* 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention". Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1980) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d 1565, 1572, 41 USPQ2d

at 1966. In the instant case, the specification does not provide a representative number of species to fulfill the written description requirement of 35 U.S.C. 112, first paragraph. Thus, the claimed nucleic acid sequences may have functions and structures that differ greatly from that of ABCA12; therefore, one of skill in the art would not be able to predictably identify the encompassed molecules as being the same as those instantly claimed.

Claims 5, 7, 9, 13, 16, 17, 47, and 51-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims encompass nucleotide probe or primers that consist of 8, 9, 10, 12, 15, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28, 30, 35, 40, 45, 50, 70, 80, 100, 200 or 500 consecutive nucleotides of any one of SEQ ID NOs: 1-4, at least 1000 nucleotides that hybridize to any one of SEQ ID NOs: 1-4 or at least 1500 nucleotides of any one of SEQ ID NOs: 1-4. The specification at pp.11 and 55 discloses nucleotide primers of a specific length.

The specification as-filed does not provide a written description for the claimed nucleic acids of 8, 9, 19, 27, 28 or 30 nucleotides, nucleic acids of at least 1000 or nucleic acids of at least 1500 nucleotides of any one of SEQ ID NOs: 1-4. The instant

claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, introduce new concepts and thus violate the written description requirement of the first paragraph of 35 U.S.C. 112.

Applicants are required to cancel the new matter in the response to this Office action. Alternatively, Applicants are invited to provide sufficient written support in the original specification for the "limitations" indicated above. At p.9 of the reply filed 21 December 2006, Applicants assert, "the claims were amended to recite probes of a particular size explicitly recited in the specification." However, nowhere in the specification is there any mention of the sequences being 8, 9, 19, 27, 28 or 30 nucleotides, at least 1000 or at least 1500 nucleotides of any one of SEQ ID NOs: 1-4. There is no written support for these claimed nucleic acid sequences. Such nucleic acid lengths are considered to be new matter.

Conclusion

No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached on Monday through Friday from 9AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner
Art Unit 1649
05 January 2007

ELIZABETH KEMMERER
PRIMARY EXAMINER